Augmenix, Inc.
Supplement 001 to K121964
TraceIT Tissue Marker

JAN 23 2013

SECTION 5.0: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitter Information

Submitter's Name:	Augmenix, Inc
Address:	204 Second Avenue Waltham, MA 02451
Telephone:	781-902-1613
Fax:	781-895-3236
Contact Person:	Eric Ankerud, Executive Vice President Clinical, Regulatory, Quality
Date of Preparation	November 19, 2012

B. Subject Device:

Trade Name:	TraceIT™ Tissue Marker
Common/Usual Name:	Tissue Marker
Class:	II
Product Code:	NEU

C. Predicate Device Name(s):

Trade Name(s)	BiomarC Tissue Marker, K001807 Coaptite Tissue Marker, K012955

D. Indications for Use:

TraceIT™ Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures. TraceIT hydrogel is intended to mark tissue for at least 3 months after injection

E. Device Description

TraceIT Tissue Marker is a sterile, single use, polymerized polyethylene glycol (PEG) hydrogel that is delivered to mark a surgical location via a needle or cannula. The hydrogel material is visible under MRI, CT, and ultrasound for up to three months after the injection. The material hydrolyzes and is cleared from the body approximately six (6) months after injection.

F. Predicate Device(s) Reference

TraceIT Tissue Marker was shown to be substantially equivalent in intended use, principle of operation, and technological characteristic to the following previously cleared devices: BiomarC Tissue Marker (K001807) and Coaptite Tissue Marker (K012955)

G. Performance Data:

In vitro and *in vivo* preclinical tests were performed to verify and validate the safety and effectiveness of TraceIT Tissue Marker and assure substantial equivalence to the predicate devices.

H. Basis for Determination of Substantial Equivalence

Upon reviewing the safety and efficacy information provided in the submission and comparing intended, principal of operation, and overall technological characteristics, TraceIT Tissue Marker is determined to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Augmenix, Incorporated
% Mr. Eric Ankerud
Executive Vice President, Clinical, Regulatory, Quality
204 Second Avenue, Lower Level
Waltham, Massachusetts 02451

January 23, 2013

Re: K121964
Trade/Device Name: TraceIt Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: November 19, 2012
Received: November 20, 2012

Dear Mr. Ankerud:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Augmenix, Inc.
Supplement 001 to K121964
TraceIt Tissue Marker

SECTION 4.0: INDICATION FOR USE STATEMENT

510(k) Number: K121964

Indication For Use: TraceIT Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures. TraceIT hydrogel is intended to mark tissue for at least 3 months after injection.

Prescription Use ___X___ (Part 21 CFR 801 SubpartD)	AND/OR	Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K121964